

Nuitiv™ Clear Needlefree Connector Pressure Integrity

Report of a study commissioned by ICU Medical, Inc. and conducted by DDL, Inc.

Background

Contrast media combined with X-ray, magnetic resonance, computed tomography, and other imaging techniques enables detailed visualization of various pathologies. Today, pressure injectors are important accessories commonly used in radiology departments to deliver contrast media into the bloodstream of patients.¹ The use of pressure injectors helps optimize image quality by controlling the pressure applied and thus the flow rate of the contrast media.²

Access to a patient's circulatory system is typically gained through a connector attached to an intravenous catheter, also known as a peripheral vein catheter, central venous catheter, or peripherally inserted central catheter.

Introduction

The purpose of this study is to evaluate the integrity of the Nuitiv™ Clear needlefree connector at the upper pressure threshold of low power pressure injectors. This study included unaged and 3-year-aged Nuitiv connectors.

This supporting information describes the methods and results for this study.

Methods

High-Pressure Liquid Test

The components used in this test were an injector, a pressure gauge, an 18-gauge catheter, and a Nuitiv Clear needlefree extension set (unaged and 3-year aged). Component setup was the following: the male end of a pressure injector with a pressure gauge was connected to a Nuitiv Clear extension set, and the male end of the Nuitiv Clear connector was attached to an 18-gauge catheter.

The component setup was subjected to an injection of a liquid with the same viscosity as contrast media [≥ 14 cP at 37 ± 3 °C]. Samples were tested to withstand a pressurized flow rate of at least 10 mL/sec, where the pressure to achieve 10 mL/sec flow should be less than 325 psi. Thirty replicates were conducted.

The acceptance criteria for the connector were to maintain a flow rate of at least 10 mL/sec for at least 10 seconds without any leaks.

Leak Tightness Test

The components used in this test were an injector, a pressure gauge, a Nuitiv Clear needlefree extension set (unaged and 3-year aged). Component setup was the following: the male end of a pressure injector with a pressure gauge was connected to a Nuitiv Clear extension set. The male end of the Nuitiv Clear extension set was occluded.

The component setup was filled with contrast media, subjected to 325 psi, and held for 10 seconds.

The acceptance criteria for the connector were to hold a pressure of 325 psi for 10 seconds without any leaks.

Results

High-Pressure Liquid Test

All 30 unaged connectors and all 30 aged connectors passed high-pressure liquid leakage testing, maintaining a pressurized flow rate of 10 mL/sec for a minimum of 10 seconds.

Leak Tightness Test

All 30 unaged connectors and all 30 aged connectors passed leak tightness testing, holding a pressure of 325 psi for a maximum of 10 seconds.

Conclusion

All samples successfully met the acceptance criteria for use with pressure injectors, making the Nuitiv Clear needlefree connector suitable for use with low power pressure injectors up to 325 psi for 10 mL/sec.

References

1. Indrajit. I et al. Pressure Injectors for radiologist: A review and what is new. Indian J Radiol Imaging. 2015.
2. Endrikat. J et al. Accuracy and repeatability of automated injector versus manual administration of an MRI contrast agent – results of a laboratory study. Investigative Radiology. 2018.